Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

Topera, Inc.
3668 S. Geyer Rd, Suite 365
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OCT 3 1 2013

Device/ classification name

- Device Name: FIRMap™ Catheter
- Product Code: MTD
- Classification Number: 870.1220
- Classification/Common name: Electrode recording catheter or electrode recording probe
- The marketed device(s) to which substantial equivalence is claimed: Constellation 510(k) - K021232, cleared 05/16/2002

Device description

The FIRMap™ Catheter is comprised of these major components,

- **Handle**
- **Handle Strain Relief**
- **Introducer Tool**
- **Catheter Shaft**
- **Basket**

The FIRMap™ Catheter is a sterile, single use device used to detect and record intracardiac electrical potentials and to deliver externally generated pacing stimuli. The distal, expandable basket assembly is, in essence, eight miniature octapolar catheters that are arranged into a three dimensional "basket" shape.. The basket assembly contains an array of 64 electrodes mounted onto eight support structures called splines.

Indications for use

For use in cardiac electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Topera FIRMap™ Catheter may also be used for delivery of externally generated pacing stimuli.

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Technological characteristics

The table below lists the technological characteristics for both the new and predicate device.

Characteristic	Proposed FIRMap™ Catheter	Predicate Device Constellation Catheter
Splines expand	Yes	Yes
No. of Splines	8	8
No. of electrodes	64	32-64
Sterile	Yes	Yes
Method of sterilization	EO gas	EO gas
Single use	Yes	Yes
Radiopaque markers	Yes	Yes
Radiopaque material	platinum-iridium alloy	platinum-iridium alloy

Performance data

Various testing has been performed (biocompatibility, dimensional, mechanical integrity, mate/de-mate, electrical safety and GLP animal study) to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to verify its conformance to the requirements for its intended use. Therefore, it has been demonstrated that the FIRMap™ Catheter is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 31, 2013

Topera, Inc.
C/O Melissa Walker
3668 S. Geyer Road, Ste 365
Saint Louis, MO 63127 US

Re: K130827
Trade/Device Name: FIRMap Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: September 13, 2013
Received: September 30, 2013

Dear Melissa Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2: Indications for Use Statement

Statement

The Indications for Use Statement:

510(k) Number: K_130827_____

Device Name: FIRMap™ Catheter

For use in cardiac electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Topera FIRMap™ Catheter may also be used for delivery of externally generated pacing stimuli.

Prescription Use ___X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.10.31 15:41:21 -04'00'

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